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Registration Decision RD2015-03

Trichoderma harzianum strain T-22

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Registration Decision for *Trichoderma harzianum* strain T-22

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Trianum Technical (containing the active ingredient *Trichoderma harzianum* strain T-22), Trianum WG Biological Fungicide and Trianum G Biological Fungicide for the suppression of soil-borne pathogens that cause root diseases on greenhouse crops, field crops, greenhouse ornamentals and turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-25. This Registration Decision[2] describes this stage of the PMRA regulatory process for *T. harzianum* strain T-22 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2014-25. This decision is consistent with the proposed registration decision stated in PRD2014-25.

For more details on the information presented in this Registration Decision, please refer to Proposed Registration Decision PRD2014-25, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website.

What is *Trichoderma harzianum* strain T-22?

Trichoderma harzianum strain T-22 is a fungus that protects plants from disease-causing fungal pathogen. It is a beneficial fungus that out competes plant pathogenic fungi for space and nutrients, colonizing the plant roots ahead of the pathogens. It also acts as a mycoparasite by producing enzymes that break down the hyphae of the plant pathogenic fungi. The mechanisms of biocontrol with *T. harzianum* are complex and generally considered in competition with plant pathogens for space and substrates in the rhizosphere, mycoparasitism and the secretion of cell wall degrading enzymes, production of antifungal substances, and induction of systemic resistance.

Trianum WG Biological Fungicide and Trianum G Biological Fungicide are end-use products for use as commercial-class biological fungicides to suppress various root diseases caused by *Rhizoctonia solani*, *Fusarium oxysporum*, *Pythium ultimum*, *P. aphanidermatum*, *P. violae* on greenhouse crops, field crops and greenhouse ornamentals as well as reducing symptoms of dollar spot (*Sclerotinia homoeocarpa*) and microdochium patch (*Microdochium nivale*) on turf. Trianum WG Biological Fungicide is applied as a suspension, while Trianum G Biological Fungicide is mixed directly into the substrate.

Health Considerations

Can Approved Uses of *Trichoderma harzianum* strain T-22 Affect Human Health?

***Trichoderma harzianum* strain T-22 is unlikely to affect your health when Trianum WG Biological Fungicide and Trianum G Biological Fungicide are used according to the label directions.**

People could be exposed to *T. harzianum* strain T-22 when handling and applying Trianum WG Biological Fungicide and Trianum G Biological Fungicide, and when ingesting treated produce. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, production of toxic by-products);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When Trianum Technical, Trianum WG Biological Fungicide and Trianum G Biological Fungicide were tested on laboratory animals, there were no signs that it caused any significant toxicity or disease.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, which are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure that the food Canadians eat is safe.

When *T. harzianum* strain T-22 was administered orally to rats, no signs that it caused toxicity or disease were observed. Secondary metabolites of toxicological significance (in other words, peptaibols) have been shown to be produced by certain naturally occurring strains of *T. harzianum* (including strain T-22). However, the use of Trianum WG Biological Fungicide and Trianum G Biological Fungicide is not expected to result in a sustained increase in levels of these peptaibols beyond the naturally occurring background levels of those produced by native *T. harzianum* strains. These metabolites are expected to be short lived in the environment once produced, as they are susceptible to ultraviolet light, high temperatures and various microbial processes in the environment. Therefore the establishment of a MRL is not required for *T. harzianum* strain T-22. As well, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are minimal to non-existent.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Trianum WG Biological Fungicide and Trianum G Biological Fungicide are proposed for use on agricultural crops, ornamentals and turf. Consequently, adults, youths and toddlers may be exposed to *T. harzianum* strain T-22 through contact on treated turf. However, risks to the general population are not of a concern since there were no signs of disease or toxicity noted in toxicological studies with Trianum Technical, Trianum WG Biological Fungicide and Trianum G Biological Fungicide.

Occupational Risks From Handling Trianum WG Biological Fungicide and Trianum G Biological Fungicide

Occupational risks are not of concern when Trianum WG Biological Fungicide and Trianum G Biological Fungicide are used according to label directions, which include protective measures.

Workers handling Trianum WG Biological Fungicide and Trianum G Biological Fungicide can come into direct contact with *T. harzianum* strain T-22 on the skin, in the eyes or by inhalation. For this reason, the product label will specify that workers exposed to the end-use products must wear waterproof gloves, long-sleeved shirts, long pants, a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter), and shoes plus socks. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Trichoderma harzianum* strain T-22 Is Introduced Into the Environment?

Environmental risks are not of concern.

Trichoderma harzianum is commonly isolated from terrestrial environments and is part of the soil micro-flora. Information available in the published literature on the environmental fate of *T. harzianum* strain T-22 suggests that, as a soil microorganism, it is likely to survive in outdoor soil under suitable environmental conditions. In other words, survival depends on the type of soil, moisture, acidity levels and temperature. Over time, however, the populations of *T. harzianum* strain T-22 should return to naturally occurring levels.

Trianum G Biological Fungicide and Trianum WG Biological Fungicide are not intended for aquatic uses and exposure to aquatic environments is limited to spray drift and run-off (following a rain event) from field applications. *T. harzianum* is not an aquatic species and is not likely to survive in aquatic environments.

Studies were conducted to determine the effects of *T. harzianum* strain T-22 on birds and bees. These studies showed that the technical grade active ingredient was not toxic or pathogenic to birds and bees.

Although non-target testing was not conducted on wild mammals, fish, some beneficial insects, microorganisms and plants, adequate information was available to determine that no significant adverse effects to these non-target organisms are expected.

Value Considerations

What Is the Value of Trianum WG Biological Fungicide and Trianum G Biological Fungicide?

Trianum WG Biological Fungicide and Trianum G Biological Fungicide, both containing *T. harzianum* strain T-22, are used preventatively for the suppression of soil-borne pathogens that cause root diseases.

Trianum WG Biological Fungicide and Trianum G Biological Fungicide are applied to soil in solution or mixed directly to the substrate, respectively. Trianum WG Biological Fungicide and Trianum G Biological Fungicide contribute to the suppression and management of plant diseases that might otherwise require applications of conventional fungicides for disease control. The use of Trianum WG Biological Fungicide and Trianum G Biological Fungicide may help reduce conventional fungicide use in greenhouses and the field.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Trianum Technical, Trianum WG Biological Fungicide and Trianum G Biological Fungicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed repeatedly to potentially large quantities of Trianum WG Biological Fungicide and Trianum G Biological Fungicide, respiratory and dermal sensitivity may possibly develop. All microorganisms, including *T. harzianum* strain T-22, contain substances that are potential sensitizers. Therefore, anyone handling or applying these products must wear appropriate waterproof gloves, a long-sleeved shirt, long pants, a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter), and shoes plus socks. In enclosed areas including greenhouses, all unprotected workers are restricted from entering areas where Trianum WG Biological Fungicide and Trianum G Biological Fungicide have been handled or applied to soil until dusts have settled.

Environment

The end-use product label will include environmental precaution statements that prevent the contamination of aquatic systems from the use of Trianum G Biological Fungicide and Trianum WG Biological Fungicide.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-25) are available for public inspection, upon application, in the PMRA Reading Room (located in Ottawa). For more information, please contact the PMRA Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada website (Request a Reconsideration of Decision), or contact the PMRA Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.